REMARKS

Reconsideration of this application is requested.

This application is a division of pending U.S. Application Serial No. 09/616,843. Page 1 of the specification has been amended to include a statement of the Cross Reference to Related Applications.

Additional pending related application are U.S. Application Serial Nos. 10/025,567 and 10/039,977 and PCT Application No. US01/49588.

U.S. Patent Nos. 5,741,489 and 6,217,865 and U.S. Patent Publication No. US2002/0012666 and publications are of record in the above noted U.S. applications. Copies of these patents, patent publication and publications along with PTO Form 1449 have been filed under separate cover. Applicants request that these patents, patent publication and publications be considered by the Examiner.

Pimentel in patent '489 discloses a method for increasing feed conversion efficiency in mammals with a diet containing an antibody produced using the enzyme urease as the antigen. *Pimentel* states that chicken antibodies are generally known to protect the recipient against bacterial infections. No antibody has been shown to increase feed conversion efficient. *Col. 2, lines 59-63. Pimentel* is limited to the use of an antibody against the enzyme urease to obtain increased feed utilization and body weight gain in animals. There is no teaching of a method of producing a microbial adherence inhibitor that promotes the growth of food animals by binding IgY immunoglobulins combined with IgM and IgA immunoglobulins to protein-wasting immunogens to inhibit the ability of the protein-wasting immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability of the immunogens to multiply.

Pell et al discloses the *E. coli*, *Listeria*, monocytogens, and *Salmonella* are major problems in the swine and poultry industries. *Pell et al* estimates that the economic costs of

salmonellosis at close to one billion dollars per year. There is no teaching in *Pell et al* to mitigate this problem and, in particular, applicants' method for production of a microbial inhibitor.

Adesiyun et al discloses that *Campylobacter* causes diarrhea in animals. A method for production of a microbial inhibitor to combat this bacteria is not suggested by *Adesiyun*.

This invention is directed to a method for the production of a microbial adherence inhibitor, in the form of chicken egg antibodies, for substantially preventing the attachment or adherence of colony-forming immunogens or haptens in the rumen and intestinal tract of host food animals and living beings. The inhibitor promotes the growth of food animals by improving feed conversion rates by decreasing the waste of dietary protein caused by the presence of certain colony-forming protein-wasting organisms in food animals.

Common bacterial immunogens which cause dramatic decreases in an animal's ability to utilize dietary protein include but are not limited to *Peptostreptococcus anaerobius*, *Clostridium aminophilium*, and *Clostridium sticklandii*. These organisms have been collectively primarily responsible for wasting up to 25 percent of the protein in cattle diets. This is a loss of as much as $25 billion annually to cattle producers and is especially apparent in grazing animals which are often deficient in protein, even though their protein intake appears to be adequate. As the host consumes protein in the diet, these deleterious organisms wastefully degrade the protein to ammonia which is converted to urea by the liver and kidneys and thus lost to the host when excreted as urine. These deleterious organisms also compete with beneficial organisms which the host needs for the efficient utilization of ammonia.

The young of chickens receive passive antibody protection through the store of antibodies placed in the eggs in which they develop from the embryonic stage. Chickens, in particular, have the ability to "load up" their eggs as they are formed, with a very large supply of antibodies concentrated many fold over that which is present in the serum of the hen. In addition, chicken antibodies are much more stable

and resistant to inactivation through digestion than mammalian antibodies, especially under adverse conditions. Once immunized the hen layers the unique IgY type immunoglobulins in the yolk while depositing the chicken IgM and IgA immunoglobulins in the albumin. The albumin IgM and IgA immunoglobulins help resistance to the whole egg preparations and help protect the avian antibodies. The entire contents of the eggs having the IgY immunoglobulins and IgM and IgA immunoglobulins administered to the food animals promote the growth of the animals by decreasing the waste of dietary protein caused by the presence of protein-wasting immunogens in the intestinal tracts of the animals. The IgY immunoglobulins bind to the protein-wasting immunogens which inhibits the ability of the protein-wasting immunogens to adhere to the intestinal tracts of the animals. The binding process is assisted and helped by the IgM and IgA immunoglobulins. In other words, the IgM and IgA immunoglobulins increase the binding of IgY immunoglobulins to the protein-wasting immunogens. Furthermore, the large quantities of antibodies which are placed in eggs are much more exclusively those specific for the antigens to which the chicken has most recently been exposed to and challenged by. This all results in the eggs of chickens being a most ideal source for large quantities of economically produced, highly specific and stable antibodies.

The method for the production of the microbial adherence inhibitor for administration to host food animals to inhibit the adherence of colony-forming immunogens in the rumen and/or intestinal tracts of the food animals comprises: first inoculating female chickens, in or about to reach their egg laying age, with the particular target immunogen. Then, after a period of time sufficient to permit the production in the chicken of antibody to the targeted immunogen, the eggs laid by the chickens are harvested. The total antibody-containing contents of the eggs are separated from the shells. The entire contents of the eggs is dried or applied as a coating on a dry carrier material. The dried separated egg antibody adherence inhibiting material may be stored or shipped for use when needed. The dried egg contents incorporating the antibody specific to the targeted immunogen is administered to the food

animals by distributing the antibody material substantially uniformly throughout an animal feed and then supplying the resulting antibody-containing animal feed to the food animals. The antibody-containing animal feed is supplied to food animals during the normal finishing schedule prior to slaughter. The substantial prevention of colonization of the targeted organism in the rumen or intestinal tract of the animal will ultimately permit elimination of the organism from the animal. This repression of colonization and elimination of the subject organisms will permit a significant decrease in wasteful degradation of the dietary protein fed to food production animals. In addition, the resulting decrease in competition to the non-ammonia producing organisms will further enhance the most efficient utilization of feed by the host.

The specification including the claims define the method for the production of the microbial adherence inhibitor for promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of colony forming protein wasting immunogen in the rumen or intestinal tracts of the animals. The control of growth the colony forming wasting immunogen in the animal boosts feed efficiency and promotes growth of the animal. *Specification, page 7, lines 3 to 17.* The target protein wasting immunogen is from a class consisting of *P.anaerobius, C.sticklandii* and *C.aminophilium.* These immunogens are described in Examples 7, 8 and 9 on pages 17 and 18 of the specification. Examples 17, 18 and 19 relate to these immunogens. *Specification, pages 23 and 24.* Organisms that colonize in the rumen and digestive tract of a host animal must possess the capability of sticking or adhering to the rumen or intestinal tract surface in order to multiply and grow. *Specification, page 9, lines 15, 16.* The organism inhibitor of the invention interferes with adherence in a highly specific manner and on a cumulative basis prevent the targeted organism from multiplying, growing and colonizing. *Specification, page 9, lines 20-22.* Immunized hens layer unique IgY type immunoglobulins in the yolk of the egg and deposit IgM and IgA immunoglobulins in the albumin. *Specification,*

page 10, lines 21-23. The albumin containing the IgM and IgA immunoglobulins helps resistance to the whole egg preparations and helps protect the avian antibodies. *Specification, page 11, line 1.* The organism inhibitor is the colonizing microorganism adhesion inhibitor that is chicken antibody, IgY immunoglobulins, which can very tightly bind to, coat, cover and obliterate adherins which attach themselves to their hosts. *Specification, page 10, lines 8-10.* The albumin IgM and IgA immunoglobulins bind in the mucus tissue of the digestive tract of the antibody containing material thereby providing a longer sustaining effect of the antibody containing material. The IgM and IgA immunoglobulins have di-sulfide bonds that retain molecules together and provide larger antibody containing molecules. The larger antibody containing molecules are more effective in preventing adherence of the targeted immunogen in the digestive tract of the animal. Albumin is a protein that protects the activity of the IgY type immunoglobulins thereby increasing their active life in the intestinal tract. The result is that use of the antibody whole egg, yolk and albumin, mixed with animal feed or water substantially prevents adherence of the targeted immunogen in the digestive tract of the animal.

An alternate embodiment of the method for the production of a microbial adherence inhibitor includes the method of coating of carrier material with the entire egg yolk and albumin. The use of the carrier material helps distribute the entire contents of the eggs in a uniform method in the animal feed. The carrier material coated with the entire contents of the eggs makes it easier for mixing with standard animal feeds. *Example 21, page 24.* The feed mixed with the carrier material coated with entire contents of the eggs is supplied to the animals. The yolk and albumin immunoglobulins bind the protein-wasting immunogens on the mucus tissue of the rumen and digestive tract of the animal thereby preventing adherence of the protein-wasting immunogen in the intestinal tract of the animal. The coated carrier material increases the duration of the effectiveness of the IgY, IgM and IgA immunoglobulins.

A further embodiment of the method for the production of a microbial adherence inhibitor includes the use of coating the mixed whole egg yolk and albumin on dry carrier material to dry the egg yolk and albumin. A separate drying process is not used prior to coating of the carrier material with the egg yolk and albumin. The elimination of a separate drying step increases the effectiveness of the immunoglobulins in inhibiting adherence immunogens in the intestinal tracts of animals.

The claims fall into three groups.

Group I comprises Claims 1, 3, 5, 8, 11, 14, 17, 20, 23, 26 and 29. These claims define a method for the production of a microbial adherence inhibitor that promotes the growth of food animals by decreasing the waste of dietary protein caused by the presence of targeted colony-forming protein-wasting immunogens. The protein-wasting immunogens are from the class consisting of *P. anaerobius*, *C. sticklandii*, *C. aminophilium*, *E. coli*, *Listeria*, *Salmonella* and *Campylobacter*. The method comprises the drying of the entire contents of eggs having yolks with IgY and albumin IgM and IgA immunogens. The entire contents of the eggs having the IgY immunoglobulins and IgM and IgA immunoglobulins administered to the food animals promote the growth of the animals by decreasing the waste of dietary protein caused by the presence of protein-wasting immunogens in the intestinal tracts of the animals. The IgY immunoglobulins bind to the protein-wasting immunogens which inhibits the ability of the protein-wasting immunogens to adhere to the intestinal tracts of the animals. The binding process is assisted and helped by the IgM and IgA immunoglobulins. In other words, the IgM and IgA immunoglobulins increase the binding of IgY immunoglobulins to the protein-wasting immunogens.

Group II comprises Claims 9, 10, 12, 13, 15, 16, 18, 19, 21, 22, 24, 25, 27 and 28. These claims include the subject matter o parent Claims 8, 11, 14, 17, 20, 23 and 26 and the process of drying the entire contents of the eggs having yolk IgY and albumin IgM and IgA immunoglobulins by coating dry feed carrier material with the entire contents of the eggs. The dry feed carrier material is from a group of

materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beat pulp. The coated carrier material increases the duration of the effectiveness of the IgY immunoglobulins and facilitates mixing with standard animal feeds.

Group III comprises Claims 6, 7 and 29 to 38. These claims define a method for the production of a microbial adherence inhibitor for promoting the growth of food animals by decreasing the waste dietary protein caused by the presence of colony-forming protein-wasting immunogens in the rumen or intestinal tracts of food animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of animals to reduce the ability of the immunogen to multiply, the immunogens include P antigen from *P.anaerobius*, CS antigen from *C.sticklandii* and CA antigen from *C.aminophilium*. The method includes providing a feed carrier material, coating the feed carrier material with the antibody and albumin of the harvested eggs. The carrier material coated with the antibody yolk and albumin is distributed substantially uniform in animal feed. The entire contents of the eggs having the IgY immunoglobulins and IgM and IgA immunoglobulins administered to the food animals promote the growth of the animals by decreasing the waste of dietary protein caused by the presence of protein-wasting immunogens in the intestinal tracts of the animals. The IgY immunoglobulins bind to the protein-wasting immunogens which inhibits the ability of the protein-wasting immunogens to adhere to the intestinal tracts of the animals. The binding process is assisted and helped by the IgM and IgA immunoglobulins. In other words, the IgM and IgA immunoglobulins increase the binding of IgY immunoglobulins to the protein-wasting immunogens. The method does not include a separate step of drying the antibody yolk and albumin as required by the method of Claims 9, 10, 12, 13, 15, 16, 18, 19, 21, 22, 24, 25, 27 and 28.

Reconsideration of the rejection of the claims under 35 USC 112 is requested. The specification of the application complies with the requirements of 35 USC 112.

Under 35 USC 112 ¶ 1 "[t]he specification shall contain a written description of the invention and the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."

The specification clearly discloses applicants' method for the production of a microbial adherence inhibitor for promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of food animals.

The Examiner has construed the requirements of 35 USC 112 to include any person skilled in the art to make and use the invention commensurate in scope with the claims. This is not the requirement of 35 USC 112 ¶ 1. It is the specification, according to 35 USC 112 ¶ 1, that contains the written description to enable a person skilled in the art to make and use the same.

The specification describes the methods of Selection of Egg laying avian hens, pages 13-14; Preparation of Stock Culture, page 14; Preparation of A antigens for Immunogens, pages 14-15; Preparation of O antigens for immunogens, pages 15-16; Preparation of A antigen for immunogen, page 16-17; Preparation of P antigen for immunogen, pages 17-18; Preparation of CA antigen for immunogen, pages 18-19; Analysis of individual eggs and serum over time; pages 19-20; Immunization of chickens with immunogens, page 21-23; and Feeding of Cattle, pages 28-29. The specification contains a detailed description and best mode of applicants' process of promoting the growth of food animals, such as cattle, by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen of intestinal tracts of the animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of the animals to reduce the ability of the immunogen to multiply. This

description enables a person skilled in the art to make and use the subject microbial adherence inhibitor.

The Examiner contends that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The specification states that the IgY immunoglobulins very tightly bind to, coat, cover and obliterate adherins which attach themselves to their hosts. *Page 10, lines 8-10.* The particular language is the "binding of IgY immunogens to protein-wasting immunogens is being increased by the IgM and IgA immunoglobulins." This function is supported by the disclosure that hen layers the unique IgY types immunoglobulins in the yolk while depositing the chicken IgM and IgA immunoglobulins in the albumin. The albumin helps resistance to the whole egg preparations and helps protect the avian antibodies. *Specification page 10, lines 21-23, page 11, line 1.* The whole egg preparation includes the IgY immunoglobulins in the yolk and IgM and IgA immunoglobulins in the albumin. The term "helps" means aids, assists and encourages the protection of the avian antibodies. This language supports the increase in the finding of IgY immunogens to the protein-wasting immunogens as more IgY immunogens are available to find to the protein-wasting immunogens.

The albumin IgM and IgA immunoglobulins increase binding in the mucus tissue of the digestive tract of the antibody containing material thereby providing a longer sustaining effect of the antibody containing material. The IgM and IgA immunoglobulins have di-sulfide bonds that retain molecules together and provide larger antibody containing molecules. The larger antibody containing molecules are more effective in preventing adherence of the targeted immunogen in the digestive tract of the animal. Albumin is a protein that protects the activity of the IgY type immunoglobulins thereby increasing their active life in the intestinal tract. The result is the use

of the antibody whole egg, yolk and albumin, mixed with animal feed or water substantially prevents adherence of the targeted immunogen in the digestive tract of the animal.

Applicants have provided a representative number of species of colony-forming protein-wasting immunogens to describe the genus identified by the terms target colony-forming immunogens. Theses immunogens are well known protein-wasting immunogens. The species of immunogens are identified as from a class consisting of: *P.anaerobius, C.sticklandii, C.aminophilium, E.coli, Listeria, Salmonella* and *Campylobacter*. This class is sufficient to identify a genus of like immunogens to a person skilled in the art. One skilled in the art would be aware of the bacterial antigens noted by *Stolle et al '018* in column 5, lines 5-35. Claims 1, 3, and 5 to 38 particularly point out and distinctly claim the subject matter of applicants' microbial adherence inhibitor as described in the specification.

Claims 1, 2, 4, 5 and 17 have been rejected under 35 USC 102(b) as anticipated by *Tokoro '895*.

Claims 2 and 4 have been canceled.

Claims 1, 5 and 17 define a method for the production of a microbial adherence inhibitor that inhibits the adherence of a targeted colony-forming immunogen in the intestinal tracts of live beings including animals. This is accomplished by using the entire contents of eggs having the IgY immunoglobulins and IgM and IgA immunoglobulins to promote the growth of the animals by decreasing the waste of dietary protein caused by the presence of protein-wasting immunogens in the intestinal tracts of the animals. The IgY immunoglobulins bind to the protein-wasting immunogens which inhibits the ability of the protein-wasting immunogens to adhere to the intestinal tracts of the animals. The binding process is assisted and helped by the IgM and IgA immunoglobulins.

Tokoro '895 discloses a method of inhibiting diarrhea in animals with bird antibody IgY

using the yolks, the albumin and the yolks of eggs. This method is related to the use of raw eggs by cattle herdpersons to treat scours (diarrhea in cattle caused by intestinal infection). *Tokoro* is directed to a specific antibody containing substance from eggs and method of production and use thereof for the prevention and treatment of colibacillosis and diarrhea in animals. There is no disclosure in *Tokoro* of an IgY immunoglobulin that binds to a colony-forming immunogen. The antibody containing substance also is used as a nutrition supplement, and as an additive to food for animals. *Tokoro* does not provide a teaching of a method for the production of a microbial adherence inhibitor for promoting the growth of food animals by binding IgY immunoglobulins combined with IgM and IgA immunoglobulins to protein-wasting immunogens, P antigen from *P. anaerobius*, CS antigen from *C. sticklandii*, and CA antigen from *C. aminophilium*, to inhibit the ability of these immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability of the immunogens to multiply. It is submitted that *Tokoro '895* does not anticipate Claims 1, 5 and 17. Claims 1, 5 and 17 are patentable over *Tokoro '895*.

Claims 1, 2, 4, 5, 8, 9, 11 and 12 have been rejected under 35 USC 102(b) as anticipated by *Stolle et al '018.*

Claims 2 and 4 have been canceled.

Claims 1, 5, 8, 9, 11 and 12 define a method for the production of a microbial adherence inhibitor that inhibits the adherence of a targeted colony-forming immunogen in the intestinal tracts of live beings including animals. This is accomplished by using the entire contents of eggs having the IgY immunoglobulins and IgM and IgA immunoglobulins to promote the growth of the animals by decreasing the waste of dietary protein caused by the presence of protein-wasting immunogens in the intestinal tracts of the animals. The IgY immunoglobulins bind to the protein-wasting immunogens which inhibits the ability of the protein-wasting immunogens to adhere to the intestinal tracts of the animals. The binding process is assisted and helped by the

IgM and IgA immunoglobulins.

Stolle et al '018 discloses a method of passive immunization of mammals using avian egg yolk antibody against any of a variety of antigens using various methods of administration under various conditions and using various compositions incorporating the antibody, after first developing in the mammal a tolerance for the antibody. The *Stolle et al* method of passive immunization of a mammal has two steps. First, the mammal is fed a material having a heterologus protein antibody obtained from the egg of a fowl immunized against an antigen until the mammal develops substantial tolerance to the antibody. Second, the mammal is administered an antibody obtained from a fowl immunized against the antigen. There is no disclosure in *Stolle et al '018* of IgY, IgM and IgA immunoglobulins with IgY immunoglobulins binding to protein-wasting immunogens to inhibit the ability of the protein-wasting immunogens to adhere to the intestinal tracts of animals. Furthermore, *Stolle et al '018* does not disclose or suggest to one skilled in the art that the binding process is assisted or helped by IgM and IgA immunoglobulins. Claims 1, 5, 8, 9, 11 and 12 are patentable over the teachings of *Stolle et al '018*.

Claims 1-2, 4-5, 17, 23 and 26 have been rejected under 35 USC 102(b) as being anticipated by:

a. *Sugita-Konishi et al*, or

b. *Yokoyama et al.*

Claims 2 and 4 have been canceled.

Claims 1, 5, 17, 23 and 26 define a method for the production of a microbial adherence inhibitor that inhibits the adherence of a targeted colony-forming immunogen in the intestinal tracts of live beings including animals. This is accomplished by using the entire contents of eggs having the IgY immunoglobulins and IgM and IgA immunoglobulins to promote the growth of the animals by decreasing the waste of dietary protein caused by the presence of protein-wasting

immunogens in the intestinal tracts of the animals. The IgY immunoglobulins bind to the protein-wasting immunogens which inhibits the ability of the protein-wasting immunogens to adhere to the intestinal tracts of the animals. The binding process is assisted and helped by the IgM and IgA immunoglobulins.

The *Sugita-Konishi et al* publication discloses IgY immunoglobulins from egg yolk from hens immunized with an infections pathogen is efficient in prevention of the disease caused by the pathogen. The IgY immunoglobulin was isolated from the egg yolk of hens immunized with 26 strains of bacteria. The investigation of the function of isolated IgY immunoglobulin was limited to three infectious bacterial strains. There is no disclosure in *Sugita-Konishi et al* of IgY, IgM and IgA immunoglobulins with IgY immunoglobulins binding to protein-wasting immunogens to inhibit the ability of protein-wasting immunogens to adhere to the intestinal tracts of animals and that the binding process is assisted or helped by IgM and IgA immunoglobulins. Claims 1, 5, 17, 23 and 26 are patentable over the teachings of *Sugita-Konishi et al.*

The *Yokoyama et al* publication discloses isolation of antibodies from chicken egg yolk. Immunoglobulin G (IgG) egg yolk was diluted with distilled water and mixed with ethyl alcohol. The mixture was centrifuged. The supernatant which contained the IgG was purified. This process does not anticipate Applicants' microbial adherence inhibitor produced by the method defined in Claims 1, 5 and 12. There is no disclosure in *Yokoyama et al* of IgY, IgM and IgA immunoglobulins with IgY immunoglobulins binding to protein-wasting immunogens to inhibit the ability of protein-wasting immunogens to adhere to the intestinal tracts of animals and the binding process is assisted or helped by IgM and IgA immunoglobulins. Claims 1, 5, 17, 23 and 26 are patentable over the teachings of *Yokoyama et al.*

Reconsideration of the following rejections of the claims as unpatentable under 35 USC

103(a) is requested.

1. Claims 1 to 3, 8, 11 and 14 are rejected as unpatentable over:

   a. *Tokoro '895* in view of *Krause et al.*

2. Claims 6-7, 9-10, 12-13 and 15-16 are rejected as unpatentable over:

   a. *Tokoro '895* in view of *Krause et al, Adalsteinsson '878* and *Betz '867.*

3. Claims 1, 6-7, 17-25, 29 and 30 are rejected as unpatentable over:

   a. *Stolle '018* in view of *Adalsteinsson '878* and *Betz et al '867.*

4. Claims 1, 6-7, 17-19 and 23-28 are rejected as unpatentable over:

   a. *Sugita-Konishi et al* in view of *Adalsteinsson '878* and *Betz et al '867*; and

   b. *Yokoyama et al* in view of *Adalsteinsson '878* and *Betz et al '867.*

There are insufficient teachings of the above combined references and no evidence of a motivating force which would impel one skilled in the art to make and use the microbial adherence inhibitor produced by the claimed method. The numerous rejections of the claims is evidence that one skilled in the art would not determine that it is obvious to make a microbial adherence inhibitor by the method of using IgY, IgM and IgA immunoglobulins in the entire contents of eggs to bind the IgY immunoglobulins to protein-wasting immunogens to inhibit the ability of the protein-wasting immunogens to adhere to the intestinal tracts of animals. The binding process is assisted and helped by the IgM and IgA immunoglobulins.

The test for determining obviousness of a claimed invention under 35 USC 103(a) is a four-part inquiring comprising (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the pertinent art; and (4) commercial considerations when such evidence is present. *Graham v. John Deere Co.*, 383 US 1 (1966); *Simmons Fastener Corp. v. Illinois Tool Works*, 222 USPQ 744 (Fed. Cir. 1984).

Obviousness cannot be properly established by locating references which describe various aspects of a patent applicant's invention without also showing evidence of a motivating force which would impel one skilled in the art to do what the patent applicant has done. Simply because one can reconstruct an invention by combining isolated teachings of references is not a basis for an obviousness conclusion unless sufficient impetus can be shown which would have led one skilled in the art to combine the teachings to make the claimed invention. *Ex Parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. 1993).

It is well established that in deciding that a novel combination would have been obvious, there must be supporting teaching in the prior art. *In re Newell*, 13 USPQ2d 1248 (Fed. Cir. 1989). The prior art must provide a suggestion to make the combination with structure shown and claimed. *CR Bard Inc. v. M3 Systems, Inc.*, 48 USPQ2d 1225 (Fed. Cir. 1998).

The Examiner has the burden under Section 103 to establish a *prima facie* case of obviousness. He can satisfy this burden *only* by showing some objective teaching in the prior art of that knowledge generally available to one of ordinary skill in the art which would lead that individual to combine the relevant teachings of the references. *In re Fine*, 5 USPQ2d 1596 (Fed. Cir. 1988).

Claims 1 to 3, 8, 11 and 14 Rejection -- 35 USC 103(a)

Claims 2 and 4 have been canceled.

Applicants' analysis, *supra*, of the primary reference, *Tokoro '895* is applicable to this rejection.

Krause et al does not disclose or suggest that IgY immunoglobulins bind to protein-wasting immunogens and that IgM and IgA immunoglobulins assist and help the binding process.

Krause et al discloses that amino acid degradation in the rumen of animals is nutritionally wasteful and produces more ammonia than the bacteria in the rumen can utilize. The excess

ammonia is converted by the animal into urea and discharged into the environment as environmental pollution. The feed additive monensin decreases ammonia accumulation in the rumen. *Krause et al* discovered that monensin inhibited growth of *P. anaerobius* and *C. sticklandii* in the rumen of an animal but did not inhibit *C. aminophilium*. The result was the reduction in the amount of ammonia in the rumen and reduction of environmental pollution. There is no teaching that monensin prevents adherence of a targeted immunogen in the intestinal tract of an animal thereby inhibiting its colony growth. Monensin does not promote the growth of food animals by preventing targeted immunogens from adhering to the intestinal tract of an animal. U.S. Patent Nos. 3,501,568 and 3,797,32 are directed to the use of monensin for promoting growth and feed efficiency of food animals. Monensin can be toxic to some animals. Feed intake of the animals is reduced as monensin cannot be added to molasses. *Specification, page 5, lines 4-12.*

It is submitted that applicants' method for the production of a microbial adherence inhibitor for promoting the growth of food animals as defined in Claims 1, 3, 8, 11 and 14 is patentable in view of the individual and combined teachings of the primary references and *Krause et al*. There are no motivating directions or suggestions in these references that would impel one skilled in the art to produce the claimed method. There is no teaching of a method of promoting the growth of food animals by binding IgY immunoglobulins combined with IgM and IgA immunoglobulins to protein-wasting immunogens to inhibit the ability of the protein-wasting immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability of the immunogens to multiply.

Claims 6 and 7 Rejection -- 35 USC 103(a)

Claim 6 has been amended to include all of Claim 1 as amended. Claim 7 depends upon Claim 6. Claim 6 defines the method to include providing a dry feed carrier material and coating

said dry feed carrier material with the separated entire contents of the harvested eggs. The dry food carrier material coated with the entire contents of the eggs inhibits the adherence of colony-forming immunogens in the digestive tracts of animals by binding IgY immunoglobulins to the colony-forming immunogens and assisting or helping the binding process with IgM and IgA immunoglobulins. The use of the carrier material helps distribute the entire contents of the eggs in a uniform method in the animal feed. The carrier material coated with the entire contents of the eggs makes it easier for mixing with standard feeds. *Example 21, page 24.* The feed mixed with the carrier material coated with entire contents of the eggs is supplied to the animals. The carrier material flows with the animal feed down the animals' digestive tracts exposing the IgY, IgM and IgM to colony-forming immunogens therein.

The method does not include the step of drying the separated entire contents of the harvested eggs before the entire contents of the harvested eggs are coated onto the dry feed carrier material. This avoids the reduction of the effectiveness of the IgY, IgM and IgA immunoglobulins caused by the process of drying the entire contents of the harvested eggs.

Claims 29 to 38 include the method of providing dry feed carrier material and coating the dry feed carrier material with the separated entire contents of the harvested eggs. The method does not include the step of drying the entire contents of the separated eggs before coating the dry carrier material with said contents of the eggs.

Applicants' analysis, *supra*, concerning the primary references, *Tokoro '895, Stolle et al '018, Sugita-Konishi et al* and *Yokoyama et al*, and secondary reference, *Krause et al*, are applicable to Claims 6, 7, 9, 10, 12, 13, 15, 16 and 29 to 38.

Adalsteinsson et al discloses a method of administering to animals an effective amount of a gastrointestinal neuro-modulator antibody to neutralize the neuro-modulator. The egg is dried into an egg powder. An example of drying is spray drying. The dried egg powder can be mixed

with animal rations or sprayed directly onto food pellets. *Col. 9, lines 31-39.* This is a mixing process wherein dry powder is mixed with animal rations which include food pellets. Applicants coat a carrier material with the entire contents of the harvested eggs. The coated carrier material is distributed into the animal feed. The animal feed mixed with the coated carrier material is supplied to the animals. The carrier material is defined in Claims 7, 10, 13, 16, 30, 32, 34, 36 and 38 as a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grain and beet pulp.

Betz et al discloses a method of making horse feed by mixing farinaceous material, proteinaceous material with fibrous materials, adding moisture, drying the mixture, and coating the combination with vegetable oil. The fibrous materials are selected from a group consisting of soy hulls, cottonseed hulls, and rice hulls. The fibrous materials provide structural strength to the feed pellets and effect stool normality. The fibrous materials are not coated with egg antibody.

Mixing dry egg powder to animal rations and coating a mixture of animal food with vegetable oil does not suggest to a person skilled in the art to coat a carrier material with IgY antibody as defined in Claims 6, 7 and 29 to 38. Claims 6, 7 and 29 to 38 are allowable over the combination of the subject prior art.

Claims 9, 10, 12, 13, 15 and 16 Rejection -- 35 USC 103(a)

Claims 9, 10, 12, 13, 15, 16, 18, 19, 21, 22, 24, 27 and 28 depend upon parent Claims 8, 11, 14, 17, 20, 23 and 26. These parent claims include the method of drying the entire contents of the eggs. The dependent claims more particularly define the drying process. The drying of the separated entire contents of the eggs is achieved by coating the dry feed carrier material with the entire contents of the eggs. Parent Claims 8, 11, 14, 17, 20, 23 and 26 define the method for the production of a microbial adherence inhibitor to promote growth of food animals by binding IgY immunoglobulins combined with IgM and IgA immunoglobulins to protein-wasting

immunogens, P antigen from *P. anaerobius*, CS antigen from *C. sticklandii* and CA antigen from *C. aminophilium*, by inhibiting the ability of these immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability of immunogens to multiply. The method of Claims 9, 10, 12, 13, 15, 16, 18, 19, 21, 22, 24, 27 and 28 includes the step of drying the separated entire contents of the harvested eggs with dry feed carrier material. The moisture of the entire harvested eggs on the dry feed carrier material is absorbed by the carrier material. This avoids the reduction of the effectiveness of IgY, IgM and IgA immunoglobulins caused by a separate drying process to dry the entire contents of the harvested eggs before coating the dry carrier material with said contents of the eggs.

The remarks concerning *Tokoro '895, Stolle et al '018, Sugita-Konishi et al, Yokoyama et al, Krause et al, Adalsteinsson et al '878* and *Betz '867* are applicable to Claims 9, 10, 12, 13, 15, 16, 18, 19, 21, 22, 24, 27 and 28. In view of the absence of a teaching of the claimed drying of antibody yolk and albumin with a dry feed carrier by *Betz et al '867* and *Adalsteinsson et al '878*, it would not have been obvious to a person skilled in the art to make and use the method claimed in Claims 9, 10, 12, 13, 15, 16, 18, 19, 21, 22, 24, 27 and 28. Applicants request that Claims 9, 10, 12, 13, 15 and 16 be allowed along with parent Claims 8, 11 and 14.

Claims 1, 6-7, 17-25, 29 and 30 Rejection -- 35 USC 103(a)

Reconsideration of the rejection of Claims 1, 6-7, 17-25, 29 and 30 as unpatentable over *Stolle '018* in view of *Adalsteinsson '878* and *Betz et al '867* is requested. Applicants' remarks concerning the teachings of *Stolle '018*, *Adalsteinsson '878* and *Betz et al '867* are applicable to this rejection. It is noted that the method defined in Claims 1, 17, 20 and 23 is not relevant to the teachings of *Adalsteinsson '878* and *Betz et al '867*. These claims do not define a dry carrier material that is covered by the entire contents of the harvested eggs. The two step passive immunization of a mammal disclosed by *Stolle '018* is substantially different from applicants'

claimed method for production of a microbial adherence inhibitor.

Claims 1, 6-7, 17-19 and 23-28 Rejection -- 35 USC 103(a)

Reconsideration of the rejection of Claims 1, 6-7, 17-19 and 23-28 as unpatentable over *Sugita-Konishi et al* or *Yokoyama et al* in view of *Adalsteinsson et al '878* and *Betz et al '867* is requested. Applicants' remarks concerning the teachings of *Sugita-Konishi et al*, *Yokoyama et al*, *Adalsteinsson et al '878* and *Betz et al '867* are applicable to this rejection. It is noted that the method defined in Claims 1, 17, 20 and 23 is not relevant to the teachings of *Adalsteinsson et al '878* and *Betz '867*. These claims do not define a dry carrier material that is covered by the entire contents of the harvested eggs.

In view of the above remarks applicants request the allowance of Claims 1, 3 and 5 to 38.

Respectfully submitted,

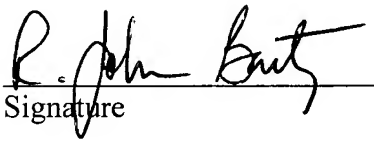
PETER NASH ET AL

By Richard O. Bartz

Richard O. Bartz
Registration No. 20,468
Southdale Office Centre
6750 France Avenue South, Suite 350
Edina, MN 55435-1983
(952) 920-3959

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on November 3, 2003,
(Date of Deposit)

Richard John Bartz
Name of applicant, assignee, or Registered Rep.


Signature

November 3, 2003
Date of Signature